IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

AMBERCARE HOSPICE, INC.,

Plaintiff,

v. No. _____

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health & Human Services,

Defendant.

COMPLAINT FOR JUDICIAL REVIEW OF ADMINISTRATIVE DECISION

Plaintiff AMBERCARE HOSPICE, INC. (the "Hospice"), by and through its undersigned counsel, files this Complaint against Defendant XAVIER BECERRA, in his official capacity as the Secretary of the United States Department of Health and Human Services (the "Secretary"), seeking judicial review of the decision rendered by the Administrative Law Judge ("ALJ") of the Office of Medicare Hearings and Appeals ("OMHA") in OMHA case number 3-8619927091 and in relation to Medicare Appeals Council ("Council") docket number M-23-777.

PARTIES, JURISDICTION, AND VENUE

1. The Hospice is a New Mexico corporation with its principal place of business located at 2129 Osuna Road Northeast, Albuquerque, New Mexico 87113.

2. At all times relevant hereto, the Hospice was a Medicare-certified company offering hospice services in New Mexico.

3. Defendant, Xavier Becerra, is the Secretary of the United States Department of Health and Human Services and the proper defendant in this action pursuant to 42 C.F.R. § 405.1136(d)(1).

4. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq*. ("Medicare Act"), and the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (the "APA").

5. Prior to filing this Complaint, the Hospice filed appeals and received determinations as to all issues presented below.

6. The Council did not issue a final decision or dismissal order or remand the case to the ALJ within 90 calendar days of receipt of the Hospice's Request for Review. *See* 42 C.F.R. § 405.1100(c). Accordingly, on March 9, 2023, the Hospice properly requested that the appeal be escalated to federal district court as permitted by 42 C.F.R. § 405.1132(a). On November 8, 2023, the Council issued an order granting the Hospice's request for escalation. The ALJ's decision is the final administrative decision and is appealable to this Court under 42 C.F.R. §1395ff(b), 42 C.F.R. §405.1132, and 42 C.F.R. §405.1136.

7. Therefore, because the Hospice has exhausted all administrative appeals and, thus, has no administrative remedy available to it, this Court is the proper forum to hear this Complaint.

8. As mandated by 42 C.F.R. §§ 405.1132(b), 1136(c)(1), this action has been commenced within 60 days of receipt of the Council's notice dated November 8, 2023 that it is not able to timely issue a final decision, dismissal order, or remand order.

9. Jurisdiction is proper pursuant to 42 U.S.C. § 1395ff(d), which authorizes judicial review of the ALJ's decision.

10. Venue is proper pursuant to 42 U.S.C. § 1395ff(b) and 42 C.F.R. §405.1136(b)(1), as the Hospice's principal place of business is located in this judicial district.

11. The amount in controversy exceeds the threshold amount of $1,850.00 for judicial review set forth in 87 Federal Register 59437 (effective Jan. 1, 2023).

LEGAL FRAMEWORK: THE MEDICARE HOSPICE BENEFIT

12. The Medicare Hospice Benefit is a benefit under Medicare Part A, a 100% federally subsidized health insurance program. It is administered by the Centers for Medicare and Medicaid Services ("CMS") on behalf of the Department of Health and Human Services ("HHS"). The Medicare Hospice Benefit pays a predetermined fee, based on the level of care provided by the hospice provider, for each day an eligible individual receives hospice care.

13. Through the Medicare Hospice Benefit, Medicare covers reasonable and necessary hospice services provided to eligible individuals. Services available under the Medicare Hospice Benefit are "comprehensive" and include (a) nursing care and services provided by or under the supervision of a registered nurse, (b) medical social services provided by a qualified social worker under the direction of a physician, (c) physician services, (d) counseling services, including bereavement, dietary, and spiritual counseling, (e) short-term inpatient care, (f) medical supplies, including drugs and biologicals, (g) home health aide / homemaker services, and (h) physical, respiratory, occupational, and speech therapy services. 42 C.F.R. § 418.202; *see also* 42 C.F.R. § 418.3; 42 U.S.C. § 1395x(dd).

14. To receive the Medicare Hospice Benefit, an eligible individual must file an election statement acknowledging that he or she "has been given a full understanding of the palliative rather than curative nature of hospice care, as it relates to the individual's terminal illness and related conditions." 42 C.F.R. § 418.24. Palliative care is "patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering[;]…addressing physical, intellectual, emotional, social, and spiritual needs[;] and…facilitat[ing] patient autonomy, access to information, and choice." 42 C.F.R. § 418.3. The election statement must also acknowledge that "certain Medicare services" are waived by the election, namely "Medicare

services that are related to the treatment of the terminal condition for which hospice care was elected or a related condition," except for services provided by the designated hospice or the individual's attending physician. 42 C.F.R. § 418.24; *see also* 42 U.S.C. § 1395y(a)(1)(c) ("[N]o payment may be made…for any expenses incurred for items or services…in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness."). Individuals are free to revoke the election of the Medicare Hospice Benefit at any time and for any reason. 42 C.F.R. § 418.28.

15. The government conditions reimbursement to providers of hospice services on a certification of hospice eligibility. 42 U.S.C. § 1395f. The Medicare Hospice Benefit is organized around benefit periods, *i.e.*, two 90-day benefit periods followed by an unlimited number of 60-day benefit periods. 42 U.S.C. § 1395d(a)(4). The hospice provider must obtain a written certification that the individual is terminally ill (a "CTI") "at the beginning of [each benefit] period" and "before it submits a claim for payment." 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.22. For the initial 90-day benefit period, a hospice provider must obtain a CTI from (1) the hospice's medical director or a physician in the hospice interdisciplinary group (a "Hospice Physician"), and (2) the individual's designated attending physician (the "Designated Attending") (if any). For all subsequent benefit periods, a CTI need only be obtained from a Hospice Physician. 42 U.S.C. § 1395f(a)(7)(A)(ii).

16. Given the nuances and complexities involved in prognostication, as described below, Congress and CMS have entrusted physicians with the responsibility to determine whether a patient meets the definition of "terminally ill." 42 U.S.C. § 1395f(a)(7); 70 Fed. Reg. 70532, 70539 (Nov. 22, 2005) ("It is the physician's responsibility to assess the patient's medical condition and determine if the patient can be certified as terminally ill."). An individual is

"terminally ill" when the Designated Attending (if applicable) and a Hospice Physician exercise their clinical judgment to conclude that "the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course." 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3. A "life expectancy" of 6 months or less means that, in the clinical judgement of the Designated Attending (if applicable) and a Hospice Physician, the individual's clinical status at the time of certification is more likely than not (*i.e.*, a probability of > 50%) to result in death within six months based on the normal course of the individual's illness. 42 C.F.R. § 418.3.

17. Several changes have been made to the Medicare Hospice Benefit over the years to ensure that Designated Attendings and Hospice Physicians who complete CTIs ("Certifying Physicians") are closely involved in evaluating individuals to predict prognosis and determine eligibility. *See, e.g.*, 75 Fed. Reg. 43236 (July 23, 2010). For example, CTIs must now include a narrative description of the individual ("CTI Narrative") and an attestation "confirm[ing] that [the Certifying Physician] composed the narrative based on his/her review of the patient's medical record or, if applicable, his/her examination of the patient." 42 C.F.R. § 418.22(b)(3)(iii). Additionally, CTIs for all 60-day benefit periods must be preceded by a "face-to-face encounter" ("F2F") in which a Hospice Physician or hospice nurse practitioner visits an individual to gather clinical findings to determine their continued eligibility for hospice care. Certifying Physicians must explain, in the CTI Narrative, why the F2F clinical findings support a life expectancy of 6 months or less. 42 C.F.R. § 418.22(a)(4) and (b)(3)(v).

18. When Certifying Physicians evaluate an individual's eligibility for hospice, they look at *prognosis*, not diagnosis. "[E]ligibility for hospice services under the [Medicare Hospice Benefit] has always been based on the prognosis of the individual, not [the] diagnosis." 78 Fed. Reg. 48234, 48245 (Aug. 7, 2013). Prognosis takes into account diagnoses and all other things

related to an individual's life expectancy. 78 Fed. Reg. 48234, 48245–46; *see also* 79 Fed. Reg. 50452, 50469 (Aug. 22, 2014) ("[T]he individual's whole condition plays a role in that prognosis."). Thus, Certifying Physicians "must consider the primary terminal condition, related diagnoses, current subjective and objective medical findings, current medication and treatment orders, and information about unrelated conditions when considering the initial certification of the terminal illness." 73 Fed. Reg. 32088, 32138 (June 5, 2008); *see also* 42 C.F.R. § 418.25(b) ("In reaching a decision to certify that the patient is terminally ill, the hospice medical director must consider at least the following information: (1) Diagnosis of the terminal condition of the patient; (2) Other health conditions, whether related or unrelated to the terminal condition; (3) Current clinically relevant information supporting all diagnoses.").

19. While a prognosis of a life expectancy of six months or less is a necessary condition for reimbursement, Congress has acknowledged that "[p]redicting life expectancy is not an exact science." *See* 142 Cong. Rec. S9582 (daily ed. Aug. 2, 1996) (statement of Sen. Breaux); *see also* 75 Fed. Reg. 70372, 70488 (Nov. 17, 2010). The phrase "if the illness runs its normal course" in the definition of "terminal illness" is an important recognition by CMS that a physician's determination of patient prognosis cannot, nor need not, be a certainty. *See* 55 Fed. Reg. 50831, 50832 (Dec. 11, 1990) (citing Government Accounting Office, *Program Provisions and Payments Discourage Hospice Participation* (Sept. 29, 1989)). CMS has also recognized that there will be variability in lengths of stay because "individuals vary in their responses to illness and care," and it is not "feasible or prudent to specify or predetermine what lengths of stay should or must be achieved to measure or evaluate the effectiveness of care provided." *See* 72 Fed. Reg. 50214, 50222 (Aug. 31, 2007). Therefore, "[t]he fact that a beneficiary lives longer than expected in itself

is not cause to terminate benefits." Medicare Benefit Policy Manual, CMS Pub. No. 100-02, Ch. 9, § 10.

20. The current Medicare framework does not preclude reimbursement for periods of hospice care that extend beyond six months. There used to be a 210-day statutory limit on hospice care, but Congress removed that limitation in 1989 in recognition of the uncertainty of prognosis. *See* 42 U.S.C. § 1395d(d)(1) (establishing that hospice providers may collect reimbursement for an unlimited number of benefit periods); *see also* Medicare Catastrophic Coverage Repeal Act of 1989; 70 Fed. Reg. 70532, 70533 (Nov. 22, 2005). In a Program Memorandum to Intermediaries/Carriers, CMS has stated:

> Recognizing that prognoses can be uncertain and may change, Medicare's benefit is not limited in terms of time. Hospice care is available as long as the patient's prognosis meets the law's six-month test. This test is a general one. As the governing statute says: "The certification of terminal illness of an individual who elects hospice shall be based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness." CMS recognizes that making medical prognostication of life expectancy is not always an exact science. ***Thus, physicians need not be concerned. There is no risk to a physician about certifying an individual for hospice care that he or she believes to be terminally ill***.

Program Memorandum Intermediaries/Carriers, Subject: Provider Education Article, CMS-Pub. 60AB (Mar. 28, 2003) (quoting 42 U.S.C. § 1395f(a)(7)) (emphasis added).

21. CMS has not created clinical benchmarks that must be satisfied to certify a patient as terminally ill. In 2008, CMS announced a rule specifying the information a Certifying Physician "must consider" in making an initial certification. *See* 42 C.F.R. § 418.102(b). CMS initially proposed labeling the considerations "criteria," but removed that word, explaining:

> In the proposed rule, we called [the considerations] "criteria," and we believe that this term may have been the source of commenter concern. Our intent was to ensure that medical directors carefully examine all relevant information that is gathered about the patient before making [an eligibility] determination…. ***We have removed the term "criteria" in order to remove any implication that there are specific CMS***

> ***clinical benchmarks in this rule that must be met in order to certify terminal illness.***

73 Fed. Reg. 32088, 32138 (June 5, 2008) (emphasis added).

22. CMS has recognized that seemingly straightforward clinical courses in a patient's condition, such as a decline or stabilization, are much more nuanced in relation to determining terminality, such that neither a lack of decline nor stabilization necessarily negate a terminal prognosis:

> [B]eneficiaries in the terminal stage of their illness that originally qualify for the [Medicare Hospice Benefit] but stabilize or improve while receiving hospice care, yet have a reasonable expectation of continued decline for a life expectancy of less than 6 months, remain eligible for hospice care. The [Certifying Physician] must assess and evaluate the full clinical picture of the Medicare hospice beneficiary to make the determination whether the beneficiary still has a medical prognosis of 6 months or less, regardless of whether the beneficiary has stabilized or improved.

See 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014) (emphasis added); *see also* 75 Fed. Reg. 70372, 70448 (Nov. 17, 2010) ("A patient's condition may temporarily improve with hospice care."); 74 Fed. Reg. 39384, 39399 (Aug. 6, 2009) ("We also acknowledge that at recertification, not all patients may show measurable decline."). Based on CMS guidance, a federal district court has excluded proposed expert testimony alleging that an individual must show decline to remain eligible for hospice. *See Vista Hospice Care*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *15 (N.D. Tex. June 20, 2016) (citing 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014)). Moreover, CMS has acknowledged that a perceived improvement or stabilization (*i.e.*, an apparent lack of decline) in symptoms may not mean that an individual's *prognosis* (on which hospice eligibility is based) has changed, and it can be difficult to distinguish a sustainable stabilization from the *impression* of stabilization that could not be maintained if the patient were to be discharged from hospice. *See* 70 Fed. Reg. 70532, 70540 (Nov. 22, 2005); *see also* 79 Fed. Reg. 50452, 50471 (Aug. 22, 2014).

23. CMS contracts with Medicare Administrative Contractors ("MACs"), which are private companies that process and pay Medicare claims on behalf of CMS. MACs issue Local Coverage Determinations ("LCDs"), which are "administrative and educational tools" that give "guidance to the public and medical community" within a specific geographical area in order "to assist providers in submitting correct claims." *See* CMS Transmittal 608, Medicare Program Integrity Manual, Ch. 13.1.3 (August 14, 2015), available at https://www.cms.gov/Regulations-and- Guidance/Guidance/Transmittals/downloads/R608PI.pdf.

24. Hospice LCDs set forth clinical *guidelines* to be considered when assessing an individual's terminality; they do not impose a set of mandatory clinical data-points that must be documented in the medical record to demonstrate hospice eligibility. LCDs do not and *cannot* establish or change the substantive legal standard for hospice eligibility because LCDs have not gone through the notice-and-comment process outlined at 42 U.S.C. § 1395hh. *See Agendia, Inc. v. Becerra*, 4 F.4th 896, 900 (9th Cir. 2021). Accordingly, eligibility for hospice cannot be limited by LCDs if an individual otherwise satisfies the only valid and substantive legal standard applicable: a determination by a physician of a prognosis of six months or less if the individual's illness runs its normal course. 42 U.S.C. § 1395x(dd)(3)(A); 42 C.F.R. § 418.3. In other words, LCDs represent only one of an indefinite number of ways Certifying Physicians may support their conclusion that an individual has a terminal prognosis under the statutory and regulatory standard. *Vista Hospice Care*, 2016 WL 3449833, at *4 ("Meeting…[LCD guidelines] is *one path* to eligibility under the [Medicare Hospice Benefit], but hospices may 'otherwise demonstrate…that the patient has a terminal prognosis.'").

25. The application of hospice LCDs to a particular individual's circumstances is a complex clinical analysis that requires the appropriate medical knowledge, skill, experience, and

expertise. Hospice LCDs—particularly the Palmetto GBA ("Palmetto") hospice LCDs that apply here—are flexible and lack the more defined thresholds and exhaustive lists of factors present in the LCDs for other Medicare items and services. In fact, the Palmetto LCDs explicitly acknowledge that the relevant diagnoses "may support a prognosis of 6 months or less under many clinical scenarios," intentionally giving Certifying Physicians clinical leeway to determine, using clinical judgment, whether the structural and functional impairments and activity limitations associated with a patient's primary hospice diagnosis, together with any secondary and/or comorbid conditions, are such that most individuals with the same or similar impairments would have a prognosis of six months or less. *See, e.g.*, Palmetto GBA's LCDs for Hospice Alzheimer's Disease & Related Disorders (L34567), Hospice - Neurological Conditions (L34547), and Hospice Cardiopulmonary Conditions (L34548).

26. Because LCDs do not establish substantive legal standards, ALJs are "not bound by LCDs," but must give "substantial deference to [LCDs] if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). If LCDs were rigid, all-or-nothing checklists for eligibility (*i.e.*, if they were to be afforded *complete* deference, rather than just substantial deference), they would (a) need to go through the § 1395hh notice-and-comment process and (b) interfere with physicians' exercise of clinical judgment. CMS was clear in the promulgation of the final rule passing the "substantial deference" regulatory standard that the standard "does not alter the ALJ's role as an independent fact finder," and that the regulation should not "lead to adjudicators 'rubber stamping' the previous appeal decision." *See* 74 Fed. Reg. 65296, 65327 (Dec. 9, 2009). LCDs themselves do not conclusively establish what is "reasonable and necessary" but, rather, are intended to serve as a "useful framework" to aid in physician decision-making regarding eligibility and facilitate ALJs' analysis of the individual facts presented to determine whether services provided were

"reasonable and necessary." *See* 70 Fed. Reg. 11419, 11458 (March 8, 2005); 42 U.S.C. § 1395y(a)(1)(A).[1]

27. Based on CMS commentary, if an individual meets LCD guidelines, then the ALJ must, in substantial deference to the LCD, determine that the individual is eligible for hospice. *See* 82 Fed. Reg. 4974, 5026 (stating that claims may be "denied in error as a result of [a reviewer's] non-compliance with…authority that is owed substantial deference, such as LCDs."). However, if an individual does not meet LCD guidelines, it does not necessarily follow that the individual is ineligible for hospice. The "substantial deference" standard requires ALJs to utilize LCDs as a basis to *allow* for reimbursement when the guidelines are met but *does not* permit ALJs to deny reimbursement solely because an individual does not squarely fall within the LCD. If, after undertaking an analysis as an independent factfinder, the ALJ determines that an individual does not satisfy LCD guidelines, the ALJ must consider all other relevant factors bearing on prognosis, including those beyond the confines of the LCD, in order to render a decision.

28. In cases where CMS or its contractors determine that an item or service is not reasonable and necessary, Section 1879 of the Social Security Act (the "Act"), codified at 42 U.S.C. § 1395pp, provides that payment shall nevertheless be made for such items or services if the provider did not know, and could not reasonably have been expected to know, that such items or services would not be covered. This liability limitation provision specifically applies to cases where CMS or its contractors determine that a Medicare hospice beneficiary was not terminally ill. 42 U.S.C. § 1395pp(g)(2).

[1] "Reasonable and necessary" is the ultimate standard ALJs are bound by under the Social Security Act for Medicare reimbursement. For hospice specifically, the standard for reimbursement is "reasonable and necessary for the palliation or management of terminal illness." 42 U.S.C. § 1395y(a)(1)(C).

29. If CMS determines a provider has been overpaid, Section 1870 of the Act, codified at 42 U.S.C. § 1395gg, allows for waiver of recoupment of the overpayment where the provider is deemed to be "without fault" with respect to creating the overpayment. A provider is "without fault" as to the creation of an overpayment, and thus entitled to waiver of recoupment of the overpayment, where it had a reasonable basis for assuming that the payments received were correct.

30. The Medicare program is administered by the Secretary through CMS which, in turn, contracts with private entities to perform certain functions on its behalf. These functions include, but are not limited to, claims processing for reimbursement submitted by Medicare providers and audits of such claims to ensure that they meet the requirements set forth in the Medicare statute and its implementing regulations.

31. Medicare claims are processed by MACs. Other CMS divisions or contractors, such as the CMS Center for Program Integrity ("CPI"), Zone Program Integrity Contractors ("ZPICs"), and Uniform Program Integrity Contractors ("UPICs") (which succeeded and replaced the ZPICs), were and are authorized by CMS to audit claims for payment presented to Medicare by health care providers relating to services they provided to Medicare beneficiaries. These audits were and are performed on a post-payment basis to ensure that the claims complied with Medicare coverage and documentation requirements at the time they were submitted for reimbursement.

32. If a CMS division or CMS contractor audits and denies a claim, the affected provider may avail itself of an administrative appeals process to contest the claim denial(s). This appeals process consists of five stages: (i) redetermination, (ii) reconsideration, (iii) a hearing before an ALJ, (iv) review by the Council, and (v) judicial review by a Federal District Court.

33. Requests for redetermination are processed by MACs. Requests for reconsideration are handled by separate contractors known as Qualified Independent Contractors ("QICs"). Hearing requests are adjudicated by ALJs in OMHA. Requests for review are processed by the Council, which is a component of the HHS Departmental Appeals Board.

STATEMENT OF FACT

34. The Hospice has continuously served Medicare hospice beneficiaries in the state of New Mexico since its founding in 1994. Currently, the Hospice provides hospice services to New Mexicans across 29 counties.

35. In letters dated August 16, 2017 and October 11, 2017, the ZPIC for Zone 4 (Health Integrity, LLC), on behalf of CMS, requested records from the Hospice pertaining to 181 claims for ten (10) patients billed to Part A of the Medicare hospice program. The claims related to services provided by the Hospice between August 22, 2014 and May 26, 2017. The records the ZPIC requested included, but were not limited to, hospice beneficiary election statements, all CTIs, referring physician documentation, the initial and all subsequent plans of care, F2F documentation, multidisciplinary visit notes and assessments (by physicians, nurses, social workers, chaplains, etc.), and interdisciplinary meeting notes. The Hospice promptly complied with this request and provided the ZPIC with thousands of pages of responsive records for review.

36. In a letter dated June 29, 2018, the Southwestern UPIC, Qlarant Integrity Solutions, LLC ("Qlarant"),[2] informed the Hospice that it denied all 181 of the claims under review. The Hospice then received a total of six demand letters from its MAC, Palmetto, between July 17 and October 30, 2018, asserting that the Hospice must refund to Medicare a total of approximately $755,158.44.

[2] Formerly known as Health Integrity, LLC. *See* Paragraph 31, *supra*, discussing how UPICs replaced ZPICs.

37. The Hospice initiated an appeal of the Qlarant's findings and Palmetto's demand letters through the Medicare administrative appeal process. On November 8, 2018, the Hospice filed a request for redetermination with Palmetto, seeking review of the denied claims. In its redetermination decision dated December 17, 2018, Palmetto upheld the denial of coverage for all claims at issue.

38. On June 12, 2019, the Hospice filed a request for reconsideration with the CMS Qualified Independent Contractor ("QIC"), C2C Innovative Solutions, Inc. ("C2C"), appealing the denied claims. In its reconsideration decision dated August 9, 2019, C2C upheld the denial of coverage as to all claims.

39. On September 17, 2019, the Hospice filed a request for a hearing before an ALJ, seeking review of all 181 denied claims pertaining to ten (10) patients. In June of 2022, the Hospice received notice that the appeal would be adjudicated by ALJ Andrea Barraclough.

40. On August 4, 2022, in advance of the two scheduled ALJ hearings, the Hospice submitted a position statement to ALJ Barraclough. The Hospice also provided a copy of the position statement to C2C. The position statement summarized certain relevant legal and medical authorities that supported the propriety of the claims at issue.

41. The position statement also introduced and attached curricula vitae from the Hospice's physician expert witness, Stephen A. Leedy, MD, MA, HMDC, FAAHPM.

42. In preparation for the ALJ hearings, Dr. Leedy applied his specialized skills and knowledge as a hospice physician to analyze all of the medical records the Hospice previously submitted to the ZPIC and the other CMS contractors. Based on his analysis, Dr. Leedy arrived at an expert opinion concerning whether the medical records supported the conclusions of the

certifying physicians that each patient at issue had a "terminal illness" during the dates of service under review.

43. The hearings took place before ALJ Barraclough on August 12 and 19, 2022. Dr. Leedy testified as an expert witness on behalf of the Hospice and was the *only* expert witness and physician to testify. No party other than the Hospice appeared at the hearings.

44. At the hearings, Dr. Leedy testified that—based on his review of the medical records and after applying his knowledge, skills, and experience as a hospice physician—the medical records supported the certifications of terminal illness and that the patients at issue had life expectancies of six months or less if their illnesses ran their normal course during the dates of service under review. Dr. Leedy further testified that the decisions by Qlarant, Palmetto, and C2C denying the claims at issue were not supported by the relevant medical records and failed to properly apply fundamental clinical and legal hospice principles.

45. Despite the unrefuted expert physician testimony supporting the propriety of the claims at issue at the hearing, ALJ Barraclough issued a decision on September 29, 2022 (the "Decision") that upheld, in whole or in part, the denial of 102 of the 181 appealed claims.

46. On November 18, 2022, the Hospice submitted to the Council a Request for Review of Administrative Law Judge Medicare Decision seeking review of ALJ Barraclough's Decision. In an exhibit to its submission to the Council, the Hospice provided additional details and examples concerning the errors ALJ Barraclough made in the Decision. That exhibit is attached hereto as Exhibit A and incorporated herein by reference.

47. The Council did not issue a final decision or dismissal order or remand the case to the ALJ within 90 calendar days of receipt of the Hospice's Request for Review. *See* 42 C.F.R. § 405.1100(c). Accordingly, on March 9, 2023, the Hospice properly requested that the appeal be

escalated to federal district court as permitted by 42 C.F.R. § 405.1132(a). On November 8, 2023, the Council issued an order granting the Hospice's request for escalation.

48. The Hospice has thus exhausted its administrative remedies, and this case is eligible for judicial review.

49. This Complaint is timely filed within 60 calendar days after the Hospice received the Council's order. *See* 42 C.F.R. § 405.1132(b).

COUNT I: VIOLATION OF THE MEDICARE ACT AND ADMINISTRATIVE PROCEDURE ACT

The ALJ Applied the Incorrect Legal Standards.

50. The Hospice hereby incorporates by reference paragraphs 1 through 49 herein.

51. The failure to apply the correct legal standards or to provide the court with a sufficient basis to determine that appropriate legal principles have been followed is grounds for reversal.

52. The ALJ applied incorrect legal standards when she committed errors including, but not limited to, those described in Exhibit A.

53. Based on this failure to apply the correct legal standards, the Decision should be reversed.

The ALJ's Decision is not Supported by Substantial Evidence.

54. The Hospice hereby incorporates by reference paragraphs 1 through 53 herein.

55. The ALJ's Decision must be supported by "substantial evidence," and where reliance is placed on one portion of the record in disregard of over-balancing evidence to the contrary, the court may reverse the Decision.

56. The unfavorable determinations in the ALJ's Decision were not supported by substantial evidence and were contrary to the overwhelming weight of the evidence, as explained

in Exhibit A. The medical records and the unrefuted expert witness testimony provided by Dr. Leedy show, by a preponderance of the evidence, that the patients had terminal prognoses of six months or less if their illnesses ran the normal course.

57. Without a rational basis, the ALJ disregarded the uncontested opinions of the only physician expert to testify at the hearing and improperly made medical conclusions she is unqualified and unauthorized to make regarding the patients' prognoses without the support of any admissible medical opinion evidence.

58. The ALJ failed to give appropriate weight and deference to the certifying physicians' clinical judgment, despite acknowledgment by Congress and CMS that a hospice physician's role is central to the Medicare Hospice Benefit.

59. As a result of the absence of substantial evidence supporting the Decision, the Decision should be reversed.

COUNT II: VIOLATION OF THE SOCIAL SECURITY ACT

The ALJ Failed to Limit the Hospice's Liability as Required by Section 1879(g)(2).

60. The Hospice hereby incorporates by reference paragraphs 1 through 59 herein.

61. Section 1879(g)(2) of the Act limits the Hospice's liability for any alleged overpayments.

62. Section 1879 provides financial relief to beneficiaries, providers, practitioners, and other suppliers who acted in good faith in accepting or providing services found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. *See* Medicare Financial Management Manual, CMS Pub. 100-06, Ch. 3 § 70.1.

63. The protection afforded under Section 1879 was expanded in 1997 specifically to guard *hospice* beneficiaries and providers from liability arising from "incorrect" diagnoses of terminal illness in cases where the beneficiary and/or provider "did not know and could not reasonably have been expected to know" that the diagnoses were incorrect. *See* 42 U.S.C. §§ 1395pp(a) and (g)(2); *see also* Cong. Rec. E1084 (June 3, 1997).

64. The ALJ's Decision fails to properly interpret and apply the limitation of liability provision of Section 1879(g)(2) in that the ALJ concluded that the Hospice knew or should have known that the services it provided to the patients at issue would not be covered by Medicare (*i.e.*, that the patients were not terminally ill) simply because it "had access to the pertinent statutes, regulations, coverage determinations, coding rules, and Medicare manuals[.]"

65. Therefore, the ALJ's Decision should be reversed, and this court should rule that the Hospice is entitled to the limitation of liability for the full value of the denied claims.

The ALJ Failed to Waive the Alleged Overpayment as Required by Section 1870.

66. The Hospice hereby incorporates by reference paragraphs 1 through 65 herein.

67. Section 1870 of the Act waives the Hospice's liability for any alleged overpayments.

68. Under Section 1870, a provider is "without fault" if it "exercised reasonable care in billing for, and accepting, the payment" (*i.e.*, it had a reasonable basis for assuming that the payment was correct). *See* Medicare Financial Management Manual, CMS Pub. 100-06, Ch. 3 § 90.

69. The ALJ's Decision does not explain how the Hospice was unreasonable in assuming that the services were reasonable and necessary and the payments correct. Specifically, the ALJ neglected to explain how notice of "the requirements for reimbursement under the

Medicare program" equates to knowledge that the specific patients at issue were not terminally ill—a determination that requires the clinical judgment of a physician, rather than the application of any CMS rule or guidance.

70. As a matter of law and fact, the Hospice is "without fault," and its liability must be waived as to all denied claims.

REQUEST FOR RELIEF

WHEREFORE, the Hospice respectfully requests that this Court:

71. Find the ALJ's Decision applied the wrong legal standards;

72. Find the ALJ's Decision was not supported by substantial evidence;

73. Reverse the decision of the ALJ that the remaining denied claims did not meet Medicare coverage guidelines for hospice services;

74. Reverse the decision of the ALJ that payment for the denied services cannot be made in accordance with section 1879 of the Act;

75. Reverse the decision of the ALJ that recoupment of the alleged overpayment cannot be waived in accordance with section 1870 of Act;

76. Hold that the Hospice is entitled to reimbursement for the claims submitted relating to Medicare that form the basis of this Complaint; and

[The remainder of this page is intentionally left blank.]

77. Grant the Hospice any other legal or equitable relief that the Court may deem just and proper.

Date: December 29, 2023.

Respectfully submitted,

By: 

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